NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. LOTUS PHARMACEUTICAL CO., LTD., and ALVOGEN PINE BROOK, LLC, Defendants.	Civil Action No: 17-6842-SDW-LDW **OPINION** December 14, 2018

WIGENTON, District Judge.

Before this Court is Defendants Lotus Pharmaceutical Co., Ltd. ("Lotus") and Alvogen Pine Brook, LLC's ("Alvogen") (collectively, "Defendants") Motion for Judgment on the Pleadings pursuant to Federal Rule of Civil Procedure ("Rule") 12(c). Jurisdiction is proper pursuant to 28 U.S.C. §§ 1331, 1338(a). Venue is proper pursuant to 28 U.S.C. §§ 1391, 1400(b). This opinion is issued without oral argument pursuant to Rule 78. For the reasons stated herein, Defendants' Motion for Judgment on the Pleadings is **DENIED** without prejudice.

I. BACKGROUND AND PROCEDURAL HISTORY

This Court writes exclusively for the parties, who are familiar with the procedural and factual history of this case, and will set forth only those facts necessary to this Court's analysis. Plaintiff Celgene Corporation ("Plaintiff" or "Celgene") holds an approved New Drug Application (NDA No. 21-880) under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 335(a), for lenalidomide capsules, which it sells under the trade name REVLIMID®.

(Compl. ¶ 24, ECF No. 1.) Defendants filed an Abbreviated New Drug Application (ANDA No. 210480) seeking approval to engage in the commercial manufacture and sale into the United States of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg lenalidomide capsules prior to the expiration of Celgene's patents (collectively, "patents-in-suit").[1] (*Id.* ¶¶ 1, 39.)

On September 6, 2017, Celgene filed a sixteen-count complaint against Defendants alleging infringement of its patents-in-suit pursuant to 35 U.S.C. § 100 *et seq.* (*See generally* Compl.) On October 5, 2017, Defendants filed an Answer, Affirmative Defenses, and Counterclaims. (Answer, ECF No. 7.) On November 9, 2017, Plaintiff filed an Answer to the Counterclaims. (ECF No. 18.) On June 21, 2018, Defendants filed the instant Motion for Judgment on the Pleadings, challenging the patent eligibility of Celgene's Risk Evaluation and Mitigation Strategy patents ("REMS Patents"): the '720 patent (Count II)[2]; the '977 patent (Count III); the '784 patent (Count IV); the '886 patent (Count IX); and the '531 patent (Count XII). (ECF No. 69.) Plaintiff filed its opposition on September 7, 2018, and Defendants replied on September 21, 2018. (ECF Nos. 82-83.)

II. LEGAL STANDARD

A litigant may bring a motion for judgment on the pleadings to determine whether a patent is valid under 35 U.S.C. § 101. *See, e.g., Data Distrib. Techs., LLC v. BRER Affiliates, Inc.*, No.

[1] The patents-in-suit cover United States Patent Nos. 5,635,517; 6,315,720 ("the '720 patent"); 6,561,977 ("the '977 patent"); 6,755,784 ("the '784 patent"); 7,189,740; 7,465,800; 7,855,217; 7,968,569; 8,315,886 ("the '886 patent"); 8,404,717; 8,530,498; 8,626,531 ("the '531 patent"); 8,648,095; 9,056,120; 9,101,621; and 9,101,622. (Compl. ¶ 1.)

[2] This Court acknowledges that on October 26, 2016, the Patent Trial and Appeal Board found that claims 1-32 of the '720 patent are unpatentable as obvious pursuant to 35 U.S.C. § 103. *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, IPR2015-01096, Paper No. 74 (P.T.A.B. Oct. 26, 2016). This Court also notes that Celgene appealed that decision on November 6, 2017.

12-4878 (JBS/KMW), 2014 WL 4162765, at *5 (D.N.J. Aug. 19, 2014). Dismissal at the pleadings stage for lack of patentable subject matter is rare. *WAG Acquistion, LLC v. Multi-Media, LLC*, Nos. Nos. 14-2340 (ES) (JAD), 14-1661 (ES) (JAD), 14-2345 (ES) (JAD), 14-2674 (ES) (JAD), 14-2832 (ES) (JAD), 15-3456 (ES) (JAD), 14-4531 (ES) (JAD), 14-3581 (ES) (JAD), 2015 WL 5310203, at *5 (D.N.J. Sept. 10, 2015) (external citation omitted). When examining a motion for judgment on the pleadings under Rule 12(c), the court examines the pleadings in the same manner as it would a Rule 12(b)(6) motion to dismiss. The court must "view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party." *Rosenau v. Unifund Corp*., 539 F.3d 218, 221 (3d Cir. 2008). Judgment may only be granted if "the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Id.* The court may rely only on the pleadings and documents integral to or relied on by the complaint. *Mele v. Fed. Reserve Bank of N.Y*., 359 F.3d 251, 256 n.5 (3d Cir. 2004) (citing *In re Burlington Coat Factory Sec. Lit.*, 114 F.3d 1410, 1426 (3d Cir.1997)).

III. DISCUSSION

Section 101 of the Patent Act provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. However, "abstract ideas are not patentable." *WAG Acquistion*, 2015 WL 5310203, at *5. The Supreme Court has established a two-step "framework for distinguishing patents that claim . . . abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 273 U.S. 208, 217 (2014) (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012)). First, courts must "determine

whether the claims at issue are directed to one of those patent-ineligible [abstract ideas]." *Id*. If so, the court must then determine "whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id*.

The REMS Patents cover the Risk Evaluation and Mitigation Strategy, which Celgene invented using computerized methods and systems "for monitoring and controlling the distribution of teratogenic drugs[.]" (Pl.'s Opp'n Br. at 1, 5, ECF No. 82.) REMS has the ability to override a doctor's issuance of a prescription for its drugs, which "has successfully prevented birth defects for more than 20 years." (*Id*. at 1.) Defendants claim that Celgene's REMS Patents are invalid because they cover an abstract idea that does nothing more than what a human could do. (Defs.' Moving Br. at 1-2, ECF No. 69-1.)

Before this Court can address the two-step process, it must first consider whether this motion is premature. Courts routinely deny § 101 motions as premature where claim construction disputes exists. *See WAG Acquistion*, 2015 WL 5310203, at *6 (denying motion to dismiss where claim construction was necessary); *Eagle View Techs., Inc. v. Xactware Sols., Inc.*, No. 15-7025 (RBK/JS), 2016 WL 4154136, at *3 (D.N.J. Aug. 2, 2016) (same). Although not mandated, "the Federal Circuit has instructed that 'it will ordinarily be desirable—and often necessary—to resolve claim construction disputes prior to a § 101 analysis, for the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter.'" *WAG Acquistion*, 2015 WL 5310203, at *6 (quoting *BanCorp Servs., LLC v. Sun Life Assurance Co. of Canada*, 687 F.3d 1266, 1273-74 (Fed. Cir. 2012)).

Here, Defendants argue that the REMS Patents do not improve the functionality of computers or other technology. (Defs.' Moving Br. at 3-6.) However, the parties have not agreed about claim construction for several terms, including the terms "computer readable storage

medium," "computer readable medium," and "generator configured to generate a prescription approval code," which is necessary to analyze the REMS Patents under *Alice*.[3] This Court cannot determine whether these patents are invalid under *Alice* without construing these terms. *See, e.g.*, *Eagle View Techs.*, 2016 WL 4154136, at *3 ("The briefing makes clear that the parties dispute the proper interpretation of the claims, such that the Court finds itself unable to develop a 'full understanding of the basic character of the claimed subject matter.'"); *WAG Acquistion*, 2015 WL 5310203, at *6 (explaining when "[i]t is clear to the Court from the parties' submissions and oral argument that the parties vigorously dispute the basic character and meaning of the claims[,]" then the Court will be unable to fairly apply the *Alice* test) (internal quotations omitted)). Although courts may construe terms in a manner most favorable to the non-moving party, this Court is "reluctant to presume, *sua sponte*, the constructions that would be most favorable." *Data Distrib. Techs.*, 2014 WL 4162765, at *8.

Moreover, as reasoned in *WAG Acquisition*, claim construction is necessary before the Court can determine whether the REMS Patents are invalid under § 101.

> It is clear to the Court from the parties' submissions that the parties vigorously dispute the basic character and meaning of the claims . . . . As such, the Court cannot fairly apply *Alice*, particularly at step two, by attempting to conjure up all plausible claim constructions at this pleadings stage in the absence of stipulated constructions or at least Plaintiff's proposed constructions of its own patent.

WAG Acquistion, 2015 WL 5310203, at *6 (quoting *Data Distrib. Techs.*, 2014 WL 4162765, at *11). Thus, Defendants' motion under § 101 is denied as premature.

IV. CONCLUSION

[3] This Court notes that Defendants adopted Celgene's construction of "prescription approval code," for purposes of this motion. (Defs.' Moving Br. at 6.)

For the reasons set forth above, Defendants' Motion for Judgment on the Pleadings is **DENIED** without prejudice. An appropriate order follows.

s/ *Susan D. Wigenton*
SUSAN D. WIGENTON
UNITED STATES DISTRICT JUDGE

Orig: Clerk of the Court
cc: Leda D. Wettre, U.S.M.J.
Parties